Digestive Disease National Coalition

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The Digestive Disease National Coalition (DDNC) is an advocacy organization comprised of the major national voluntary and professional societies concerned with digestive diseases. The DDNC focuses on improving public policy and increasing public awareness with respect to diseases of the digestive system.

The DDNC's mission is to work cooperatively to improve access to and the quality of digestive disease health care in order to promote the best possible medical outcome and quality of life for current and future patients.

The Coalition would like to take this opportunity to comment on this request for information, and more specifically, the section below:

"What considerations should the Departments and OPM take into account in defining "rebates, fees, and any other remuneration"? Should bona fide service fees—for example, administrative fees, data sharing fees, formulary placement fees, credits, and market share incentives—be included in this definition? Are there additional fees that the Departments and OPM should include in this definition? How should manufacturer copay assistance programs and coupon cards be accounted for? How should copay accumulator programs be accounted for?"

The DDNC has advocated strongly against all cost-shifting tactics that unnecessarily take money out of the pockets of patients, and co-pay accumulator programs are one of these harmful tactics. Patients with costly health conditions often utilize co-pay assistance to help pay for their medications. Recently, payers have enacted "co-pay accumulator adjustment programs" to prevent patients from being able to apply these payments to their deductibles and out-of-pocket maximums and forcing them to take on more of the cost themselves.

The DDNC recently published a White Paper titled "Patient Access to Care and Treatments in the Cost-Shifting Era", and we have provided that White Paper as an attachment to this submission for a thorough look at cost-shifting tactics. An excerpt from the White Paper on co-pay accumulators is included below:

"Cost shifting has existed for more than 20 years and occurs when a firm raises its prices to one buyer because it lowers the price to another buyer. Cost-shifting is a component of cost-sharing, which is the amount or percentage an insured person must pay toward prescription drugs that are covered by a health insurance policy.

In 2018, pharmacy benefit managers (PBMs) rolled out new copay accumulator adjustment programs. These target specialty drugs for which a manufacturer provides copayment assistance. Plan sponsors—employers and health plans save big money because accumulators shift a majority of drug costs to patients and manufacturers. It also prevents patients from being able to apply these payments to their deductibles and out-of-pocket maximums which forces them to take on more of the cost themselves. Accumulator adjustment programs will further lower a plan's drug spending by discouraging the appropriate utilization of specialty therapies and reducing adherence. These programs also go by a variety of other names, including, "out of pocket accumulators," "co-pay maximizers," and "specialty copay card programs."

The median U.S. household income is about \$58,000. It's clear that many will struggle to pay thousands of dollars out-of-pocket in the middle of a benefit year. QVIA analyses demonstrate that this phenomenon is already occurring. More than one in four specialty brand prescriptions are abandoned during the deductible phase. That is three times the rate of prescription abandonment when there is no deductible. Higher utilization of specialty drugs is usually considered a positive trend. That is because it is well established that pharmaceutical spending reduces medical spending and improves patients' health. The massive cost-shifting to patients, however, will reduce spending by decreasing the utilization of specialty drugs but lead to poorer outcomes for the patients including health deterioration and hospitalization, as well as increased system costs."

Patients managing chronic and complex medical conditions often don't have the resources to navigate these medically-questionable and complicated maneuvers that shift costs onto the patient. Most chronic disease patients struggle just to afford their existing medical costs, and they frequently defer essential treatment in order to pay for everyday expenses like groceries and housing. DDNC urges the Administration to address these and future tactics in a proactive manner that prevents further cost-shifting aimed at patients suffering from digestive diseases and other chronic health conditions.

Sincerely,

Ceciel Rooker Chairperson

Ceciel TRooker.

Bryan Green, MD President